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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/989,674	11/21/2001	Gordon L. Woods	2404-105	1175

6449 7590 01/29/2002

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EXAMINER

JIANG, SHAOJIA A

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 01/29/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application N .

09/989,674

Applicant(s)

WOODS, GORDON L.

Examiner

Shaojia A. Jiang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-63 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-63 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

This application is a continuation in part of 09/610538 which claims priority to provisional application Serial No. 60/142,926.

### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-11 and 56 drawn to a method of decreasing the PGE2:PGE2 $\alpha$  ratio and zinc:cadmium ratio in the body fluid of a mammal, classified in class 424, subclass 654.
- II. Claims 12-16 drawn to a method of regulating the concentration of zinc-containing and PEG2-dependent matrix metalloproteinases in the body fluid of a mammal, classified in class 424, subclass 654.
- III. Claims 17-19 and 60 drawn to methods of regulating and correcting the concentration of zinc in the body fluid and tissues of a mammal, classified in class 424, subclass 654.
- IV. Claims 20-25 and 61 drawn to methods of regulating and correcting the concentration of zinc in the body fluid and tissues of a mammal, classified in class 424, subclass 654.
- V. Claims 26-35 drawn to a method of screening a person for indication of or a risk of developing a disease associated with a cadmium deficiency, classified in class 424, subclass 654.

- VI. Claims 36-38 drawn to a method of regulating the influx of extracellular calcium into cells in the body of a human, classified in class 424, subclass 654.
- VII. Claim 39-41 drawn to a method for preventing or delaying the onset of prostate, colon or breast cancer in a human, classified in class 424, subclass 654.
- VIII. Claim 42 and 47-54 drawn to a method for preventing or slowing the progress of a disease associated with above-normal systemic levels of zinc in a human, classified in class 424, subclass 654.
- IX. Claim 43 drawn to a method for preventing or delaying the onset of osteoporosis in a human, classified in class 424, subclass 654.
- X. Claim 44 drawn to a method for preventing or delaying the onset of diabetes in a human, classified in class 424, subclass 654.
- XI. Claim 45 drawn to a method for preventing or delaying the onset of hypertension in a human, classified in class 424, subclass 654.
- XII. Claim 46 drawn to a method for preventing or delaying the onset of Alzheimer's disease in a human, classified in class 424, subclass 654.
- XIII. Claim 55 drawn to a method for inhibiting cancerous tumor growth in a human, classified in class 424, subclass 654.
- XIV. Claim 63 drawn to two compositions comprising specific components herein, classified in class 424, subclass 654.

Claims 57-59 link(s) inventions Groups I, II, III and VI. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s) 57-59. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Inventions Group I- XIV are unrelated to each other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions are separate and distinct each from the other because they have different modes of operation and different functions.

Each method of treatment relates to a separate and distinct area of pharmaceutical technology. The search for all inventions would place an undue burden

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on the examiner in view of the diversity of the medical disorders to be treated and the corresponding diversity in the field of search for each.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Because the above restriction/election requirement is complex, a telephone call to applicant's agent to request an oral election was not made. See M.P.E.P Sec. 812.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, Ph.D. whose telephone number is (703)305-1008. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

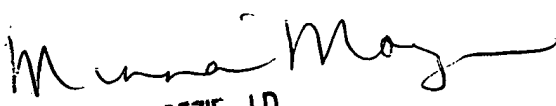
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703)308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)305-1235.

Shaojia A Jiang  
Patent Examiner, AU 1617  
January 26, 2002

  
MINNA MOEZIE, J.D.  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600